

TWELVE MONTH SAFETY AND EFFICACY OF LOW DOSE MIFEPRISTONE FOR UTERINE FIBROIDS

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OBJECTIVES

To assess long-term effects of low dose mifepristone on fibroid regression, symptoms, and endometrial pathology.

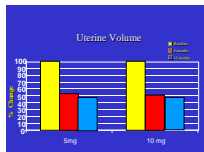
METHODS

Prospective, open-label, trial of 5 vs 10 mg mifepristone daily for 1 year, in 40 women with large, symptomatic fibroids. Measurements were made by ultrasound determination of the total volume of the uterus. Symptoms were assessed by questionnaire. Endometrial pathology was determined by endometrial biopsy. A subset of subjects was followed after cessation of mifepristone therapy.

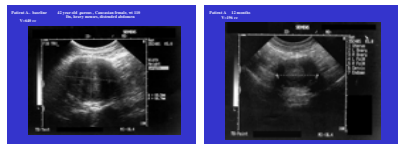
RESULTS

All therapeutic effects pre and post treatment were statistically significant.

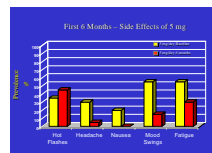
Mean uterine volumes decreased by 48-49 % after 6 months and by 52-53% after 12 months.



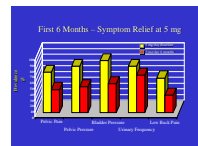
Typical ultrasound results



Most expected side effects of mifepristone were reduced at 6 months.

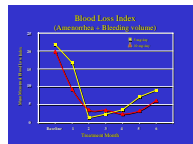


Prevalence and severity of all symptoms of leiomyomata decreased from registration through 6 months.

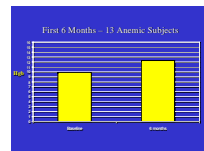


RESULTS

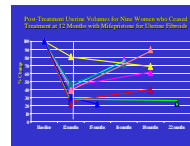
Amenorrhea occurred in 61-65% at 6 months, and 40-70 % at 12 months.



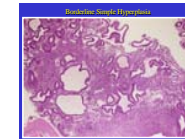
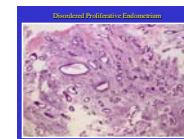
Anemia was corrected in all anemic subjects.



Nine women were followed post-treatment for an average of 5.7 months. Uterine volumes increased among most of these subjects, though remained on average 42% less than baseline.



Eighty endometrial biopsies were performed. Simple hyperplasia was seen in 5 of 36 (13.9 %) subjects at 6 months; all cases occurring in the 10 mg group (Fisher exact P test = 0.04). At 12 months 1 of 21 (4.8 %) subjects had minimal hyperplasia, also in the 10 mg group (Fisher exact P test = 0.48). No endometrial sample showed cytologic atypia.



CONCLUSIONS

Long-term administration of low dose mifepristone results in fibroid shrinkage and amelioration of symptoms, modest rates of low-grade endometrial hyperplasia, but no evidence of atypia. Regrowth occurs following cessation of the drug, although slowly in some subjects. Mifepristone may be a useful treatment for fibroids. Further studies are required to assess quality of life improvement, to clarify the optimal dose, and to assess the value of interrupted therapy or progestin withdrawal.

